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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,796	01/11/2002	Naida M. Loskutoff	13511.1USU1	8344

23552 7590 07/25/2007

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
1657	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/044,796	LOSKUTOFF ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,9,11,14,21,22,24-26,28-31 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4, 5, 9, 11, 14, 21, 22, 24-26, 28-31 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 4, 5, 9, 11, 14, 21, 22, 24-26, 28-31 and 33 as amended (5/07/2007) are pending and under examination.

Claim Rejections - 35 USC § 112

New matter

Claims are rejected under 35 U.S.C. 112, *first paragraph*, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation directed to the use of the entire concentration range 0.001 % to 1 % of sulfate-containing anionic surfactant in the semen extender composition with lecithin has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus that would show possession of the concept of the use of the entire concentration range 0.001 % to 1 %" of sulfate-containing anionic surfactant.

The generic disclosure of the as-filed specification (page 6) describes a variety of surfactant including anionic, cationic, nonionic, etc. (page 6) with nonionic surfactant including glycerol esters and tween 80 as preferred for the semen extender compositions. However, the claimed concentration range 0.001 % to 1 % is linked to the use of nonionic surfactant as disclosed (page 6, line 25-31). There is only one disclosed range for sulfate-containing surfactant such as 0.01% - 1% of sodium lauryl sulfate (page 12, line 17).

This is not sufficient support for the entire range as presently claimed. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of directed to the use of the entire concentration range 0.001 % to 1 % of sulfate containing anionic surfactant in the semen extender composition with lecithin is considered to be the insertion of new matter for the above reasons.

Please see *Gentry Gallery v. Berkline* 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification.

Applicant is hereby notified that the insertion of new matter into the claims has necessitated the removal of the art rejection over the instant claims. However, removal of new matter might result in the reinstatement of the art rejection(s).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 5, 9, 11, 14, 21, 22, 24-26, 28-31 and 33 as amended remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 685 556 (Ghazarian) taken with US

3,444,039 (Rajamannan), US 6,130,034 (Aitken), US 6,140,121 (Ellington et al) and the reference by Hellmann et al. (Zuchthg., 1988, 23: 33-37).

Claims are directed to a semen extender composition that comprises a non-animal derived phospholipids such as lecithin in amounts of about 0.1-6%, about 0.0001-1% of anionic sulfate-containing surfactant, about 0.5-3% of carbohydrate, about 3-14% of freeze-agent and a buffer to provide for pH of about 6.9-7.2 and osmolarity of about 250-350 mOsm. Some claims are further drawn to the use of 90% water in the composition. Some claims are further drawn to the use of anionic sulfate-containing surfactant comprising sodium lauryl sulfate. Some claims are further drawn to the use of antioxidants such as vitamin A or vitamin E in the semen extender composition. Some claims are further drawn to the use of freeze-agent such as glycerol. Some claims are further drawn to incorporation of semen into the semen extender composition. Some claims are/are further drawn to the method of making the semen extender composition by mixing the components of the composition.. Some claims are further drawn to the use of to the use of specific concentrations of anti-oxidant(s) in the semen extender composition.

EP 0 685 556 (Ghazarian) discloses a semen extender composition that is substantially free from animal products and that contains soybean lecithin as a source of phospholipids. The semen extender composition also contains a mixture of Tris and sodium citrate as surfactant and buffer. The semen extender composition contains carbohydrate component such as glucose, fructose and lactose and the freeze agent component such as glycerol (see EP page 3, lines 4-16; or see translation page 6). The amounts of ingredients in the cited semen extender composition are within the ranges of the claimed semen extender composition, for example: about 0.6-0.8% of phospholipids such as lecithin, about 0.5% of total carbohydrate, about 6-7% of freeze-agent

or glycerol. Lecithin is also antioxidant. Although the cited patent is silent with regard to pH and osmolarity of the semen extender composition and/or solution for semen preservation, the values of pH and osmolarity that are claimed are regular parameters that are commonly used for animal cell culture maintenance and preservation. The cited EP patent also teaches the method of making the semen extender composition by mixing the components of the composition. The cited EP patent also teaches incorporation of semen into the semen extender composition (example 3).

The cited EP 0 685 556 is lacking particular disclosure about the use of a sulfate-containing anionic surfactant.

However, the reference by Hellmann et al. teaches the use of a sulfate-containing anionic surfactant such as sodium lauryl sulfate in the composition intended for animal semen preservation (see English abstract) in amounts 0.2% (see OEP product in notes to figures 1 and 2). The reference teaches that incorporation of sodium lauryl sulfate had a significant effect on acrosome integrity of frozen and thawed semen (English abstract).

The composition of the cited EP 0 685 556 contains lecithin that is also antioxidant. It is well known to incorporate vitamins as antioxidants into semen extender compositions. For example: the cited patent US 6,130,034 (Aitken) teaches incorporation of antioxidant such as vitamin E, for example: see col. 1, line 50, as a commonly used and/or regular component in the composition intended for semen transportation and storage (col. 1, line 29). The suggested concentration for anti-oxidant vitamin E is 1mM (col. 1, line 54). Further, US 6,140,121 (Ellington et al]) also teaches incorporation of vitamins (entire document including col.17, line 11).

In addition, US 3,444,039 is relied upon to demonstrate that sodium citrate buffering preparation that is commonly used composition intended for semen preservation including semen extender compositions of EP 0 685 556 and/or US 6,368,786 provides for neutral pH of about 6 - 7 and osmolarity of about 250-300 mOsm which are regular pH and osmolarity parameters for animal cell culture maintenance and preservation (see col. 2, line 6 or see col. 3, line 30 and 44). And the cited US 6,140,121 (Ellington et al) teaches incorporation of various buffers into compositions intended for semen preservation including buffers such as EDTA (col. 19, line 28) or Tris or sodium citrate as well as surfactant (Tween 80) within the medium M199 in the composition intended for freezing sperm (col. 16, lines 57-59).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to incorporate ingredients such as a sulfate-containing anionic surfactant or sodium lauryl sulfate and various antioxidants or vitamins as required by the presently claimed invention with a reasonable expectation of success in obtaining composition suitable for semen maintenance and/or preservation because all claimed ingredients have been known and commonly used in the field of semen maintenance and preservation as adequately demonstrated by the cited references in combination.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references.

Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicants' arguments filed 8/18/2006 have been fully considered and the contents of Declaration by Dr. Richard B. Lomneth filed 4/04/2005 and supplemental declaration filed 5/07/2007 have been reviewed but they are not all found persuasive for the reasons below.

1. Claim rejection under 35 U.S.C. 102(b) as being anticipated by EP 0 685 556 (Ghazarian) has been withdrawn because the cited composition does not include a sulfate-containing anionic surfactant.

2. Claim rejection under 35 U.S.C. 102(e) as being anticipated by US 6,368,786 (Saint-Ramon et al.) has been withdrawn because the cited composition does not include a sulfate-containing anionic surfactant.

3. With regard to claim rejection under 35 USC § 103 applicants argue that there is no suggestion to combine references (response pages 11-13). However, the cited references are in the same field of endeavor (such as compositions intended for semen storage or preservation) and they seek to solve the same problems as the instant application and claims (such as provide for a semen extender composition), and one of skill in the art is free to select components available in the prior art, *In re* Winslow, 151 USPQ 48 (CCPA, 1966).

In particular, with regard to EP 0 685 556 (Ghazarian) applicants argue that is fails to disclose the use of an "anionic surfactant". This argument is not found persuasive because the prior art as a whole recognizes incorporation of surfactants including incorporation specific anionic surfactant such as sodium lauryl sulfate into the semen extender composition as adequately taught by the reference by Hellemann et al., for example.

With regard to the cited patents US 3,444,039 (Rajamannan), US 6,130,034 (Aitken) and the reference by Hellmann et al applicants appear to argue (response pages 12-13) that the cited compositions contain animal derived phospholipids from egg yolk. However, these prior art references are relied upon for the teaching about other than phospholipids components as explained above. Moreover, the cited US 6,140,121 (Ellington et al) and EP 0 685 556 (Ghazarian) clearly teach the exclusion of egg products since the animal products including egg products could carry pathogens. For example: see US 6,140,121 at col. 27, line 16-30. The cited EP 0 685 556 discloses compositions with non-animal derived phospholipids such as soy lecithin and the cited US 6,140,121 (Ellington) clearly suggests incorporation of soy lecithin as alternative to egg yolk for the non-egg yolk containing semen extenders (col. 27, lines 20-30).

Motivation to combine the prior art teaching can come not only from direct teaching of the prior art, but also the nature of the problem to be solved and/or the knowledge of persons of ordinary skill in the art, Ruiz v. A.B. Chance Co. 357 F.3d 1270, 69 USPQ2d 1686 (2004). Further, the examiner recognizes that references cannot be arbitrarily combined that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references, *In re* Nomiya, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. One test for combining references is what the combination of disclosures taken as a whole would suggest to one versed in the art, rather than by their specific disclosures, *In re* Bozek, 163 USPQ 545 (CCPA 1969). In this case, the use of components known in the art, and used for their known art specific properties even in different combinations, is considered to be obvious in the absence of evidence to the contrary.

The Declaration by Dr. Richard B. Lomneth filed 4/04/2005 and supplemental declaration filed 5/07/2007 have been reviewed. Applicants presented these Declarations as the evidence intended to demonstrate reduction to practice of the instant patent application prior to May 14, 1999 (priority date of US 6,368,786). Claim rejections over US 6,368,786 (Saint-Ramon et al.) has been withdrawn because the teaching of this patent is redundant to the cited EP 0 685 556 (Ghazarian) and because the composition or US 6,368,786 does not include a sulfate-containing anionic surfactant.

Furthermore, with respect to the contents of the Declaration by Dr. Richard Lomneth (filed 4/04/2005) it is noted that the particular compositions reported in Declaration (4/04/2005) appear to be different from the particular embodiments and compositions disclosed in the instant specification (pages 17-19) to consider the possibilities of unexpected results, if any. Thus, the advantage that is not disclosed in the specification cannot be urged as basis for allowing claims. *In re Lundeberg*, 117 USPQ 190 (CCPA 1958).

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

July 20, 2007

VERA AFREMOVA

PRIMARY EXAMINER